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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,340	06/08/2001	Thomas Bock	4420.000600	1031

23720 7590 10/01/2003

WILLIAMS, MORGAN & AMERSON, P.C.
10333 RICHMOND, SUITE 1100
HOUSTON, TX 77042

EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/01/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/877,340

Applicant(s)

BOCK ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-35 are pending.

Election/Restriction

Upon considering the claimed inventions, restriction is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to an HBV variant, classified in class 424, subclass XXX.

Upon election of Group I, further restriction/election for one single formula of an HBV variant is required under 35 U.S.C. 121:

- a). Formula I,
- b). Formula II.

Upon election of Group a), further restriction/election for one combination of one single mutation from each listed B1 to B16 is required under 35 U.S.C. 121. For example, a elected combination is L for B1, E for B2, Y for B3 etc.

Upon election of Group b), further restriction/election for one combination of one single mutation from each listed X, and Z1 to Z50 is required under 35 U.S.C. 121. For example, a elected combination is N for Z1, I for Z2, V for Z3 etc.

The above further election is not a species election because each variant of HBV has different structure due to different mutation in the sequence. The search for one kind of variant with one sequence does not need to search other mutated HBV sequence. Moreover, search for all mutants will constitute a serious burden for the Office because an extensive search for each mutated HBV by sequence has to be conducted both in house and in commercial database.

- II. Claim 6, drawn to a method for determining whether an HBV strain exhibits sensitivity to a nucleotide analogue, classified in class 435, subclass 7.93.
- III. Claim 7, drawn to a method for detecting an anti-HBV agent by constructing a genetic construct comprising a replication competent-effective amount the genome from a HBV in a plasmid, classified in class 435, subclass 5.
- IV. Claim 8, drawn to another method for detecting an anti-HBV agent by constructing a genetic construct comprising a replication competent-effective amount the genome from a HBV in a baculavirus genome, classified in class, 435, subclass 60.1.

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- V. Claim 9, drawn to a method for detecting an anti-HBV agent by generating a continuous cell line comprising an HBV genome, classified in class 435, subclass 325.
- VI. Claim 10, drawn to a method for treating a patient infected with HBV comprising administering an effective amount of a nucleoside analogue, classified in class 514, subclass 44.
- VII. Claim 11, drawn to a method for treating a subject infected with HBV comprising administration of an effective amount of FAM and/or LAM, classified in class 514, subclass 11.
- VIII. Claim 12, drawn to a method for treating a subject infected with HBV by administering an anti-HBV agent in combination with an agent, classified in class 424, subclass 93.1.
- IX. Claim 13, drawn to a method for using an HBV variant, classified in class 435, subclass 4.
- X. Claims 14-17 drawn to a computer program product for assessing the likely usefulness of viral variant or a biological sample comprising the same, classified in class 702, subclass 183.
- XI. Claims 18-21, drawn to a computer, classified in class 709, subclass 1.
- XII. Claims 22-27, drawn to a computer readable program, classified in class 702, subclass 137.
- XIII. Claims 28-31, drawn to a computer programmed to perform a method for assessing the HBV variant, classified in class 702, subclass 128.
- XIV. Claims 32-35, drawn to a computer system programmed to perform a method for assessing the usefulness of a HBV variant, classified in class 713, subclass 186.

The inventions are distinct, each from the other because of the following reasons:

Inventions of groups a) and b) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are directed to structurally different products. They require different searches and have different patentable weights.

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Inventions of groups I and X-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are directed to structurally different products, e.g. the product of Group II is an HBV variant, whereas the product of the group X is a computer program.

Inventions of groups II and III-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are directed to different methods by using different procedures with different purposes, e.g. the method of Group II is determining whether an HBV strain exhibits sensitivity to a nucleotide analogue, whereas the method of Group VII is for treatment of HBV infection.

Inventions of I and VII are related as process of using and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be practiced with materially different product or (2) that the product as claimed can be practiced by another and materially different process (MPEP § 806.05(f)). In the instant case, the process of Group VII as claimed can be practiced with materially different product, such as INF- λ , rather than FAM and/or LAM.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for one of the Groups are not required for another one of the Groups, restriction for examination purposes as indicated is proper.

The inventions are distinct, each from the other because of the following reasons:

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'Bao Qun Li', is written over the printed name.

Bao Qun Li

September 30, 2203